Exhibit E

PEGGY PENCE, PhD, RAC, FRAPS
EXPERT WITNESS REPORT

RE: TENSION FREE VAGINAL TAPE (TVT) SYSTEM
PRODUCT LIABILITY LITIGATION
vs. ETHICON, INC.
AND JOHNSON & JOHNSON
(Collectively referred to in this Report as Ethicon)

2. ***General Device Labeling: 21 CFR Part 801***

General labeling requirements for medical devices have been established in 21 CFR Part 801. Guidance on "Indications for Use," "Contraindications," "Warnings," "Precautions," and "Adverse Reactions" paraphrase applicable provisions in the labeling requirements for prescription drugs.[29]

A premarket notification must normally only contain proposed labeling sufficient to describe the device's intended use, as discussed in the "Blue Book" 510(k) Memorandum #K86-3 dated June 30, 1986.[30] Accordingly, a 510(k) finding of substantial equivalence does not connote approval of the proposed labeling. However, in the case of devices with special labeling requirements and devices for which inclusion of specific directions for use, contraindications, warnings, etc., in the labeling may be critical to a finding of equivalence, CDRH's Office of Device Evaluation (ODE) 510(k) labeling review includes an evaluation of compliance of the proposed labeling or portions thereof, as appropriate.

In contrast, specific labeling is approved as part of a PMA. While FDA will approve a PMA on the basis of draft final labeling if the only deficiencies concern editorial or similar minor deficiencies in the draft final labeling, PMA approval depends on incorporation of the specific labeling changes exactly as directed and the manufacturer is required to submit to FDA a copy of the final printed labeling before marketing.[31] Labeling changes that affect the safety or effectiveness of a device require a PMA supplement and can be done without FDA approval via a Special PMA Supplement only when such modifications are based on newly acquired information and evidence of a causal relationship between the product and a safety signal. New information "must reveal risks of a different type or greater severity or frequency than previously included in submissions."[32,33] Importantly, routine review of patient labeling for all original PMAs and panel-track supplements will be conducted by the FDA Division of Device User Programs and Systems Analysis (DDUPSA) when human factors for the usability of the device need to be considered.[34]

3. ***Patient Labeling***

FDA issued a guidance in April 2001, titled "Guidance on Medical Device Patient Labeling," to assist manufacturers in their development and FDA reviewers in their review and evaluation of patient labeling, "to help make it understandable to and usable by patients," and lay caregivers as applicable.[35] Medical device patient labeling is any information associated with a device

---

[29] 21 CFR Part 201; Device Labeling Guidance 3/8/91 [G91-1] – Blue Book Memo.
[30] Guidance on the CDRH Premarket Notification Review Program 6/30/86 [K86-3]: 510(k) Memorandum #K86-3.
[31] FDA Device Advice: Device Regulation and Guidance. PMA Labeling http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050390.htm.
[32] 21 CFR § 814.39 PMA Supplements.
[33] Modifications to Devices Subject to Premarket Approval (PMA)-The PMA Supplement Decision. Dec 11, 2008 http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089274.htm#4e.
[34] FDA Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #69-3).
[35] Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers. Document issued on: April 19, 2001.